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ILLUMINA, INC. 9885 TOWNE CENTRE DRIVE SAN DIEGO, CA 92121-1975				STEELE, AMBER D
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/767,476	STUELPNAGEL ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Amber D. Steele	1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 29 October 2007.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 29-75 is/are pending in the application.
  - 4a) Of the above claim(s) 60-75 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 29-59 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>10/29/07; 12/17/07</u> .	6) <input type="checkbox"/> Other: _____

**DETAILED ACTION**

***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 29, 2007 has been entered.

***Status of the Claims***

2. Claims 1-28 were canceled and new claims 29-50 were added in the preliminary amendment received on January 28, 2004.

In the amendment to the claims received March 9, 2007, claims 29 and 41 were amended and new claims 51-58 were added.

In the amendment to the claims received on October 29, 2007, claims 29, 41, 51, and 55 were amended and new claims 59-75 were added.

Claims 29-75 are currently pending.

Claims 29-59 are currently under consideration.

***Election/Restrictions***

3. Newly submitted claims 60-75 are directed to inventions that are independent or distinct from the invention originally claimed for the following reasons:

I. Claims 29-59, drawn to an array of arrays, classified in class 506, subclass 13.

- II. Claims 60-67, drawn to a method of making an array of arrays via providing a plurality of arrays and placing each on a solid support, classified in class 506, subclass 23.
- III. Claims 68-75, drawn to a method of making an array of arrays via providing a substrate and modifying the surface, classified in class 506, subclass 27.

4. The inventions are distinct, each from the other because of the following reasons:  
Inventions II-III (processes) and I (product/apparatus) are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product as claimed can be made by a materially difference process (i.e. a method of printing an array in each well of a multiwell plate and/or on projections of a surface).

5. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;

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- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

6. Since applicant has received an action on the merits for the originally presented invention (i.e. Group I), this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 60-75 are withdrawn from consideration as being directed to non-elected inventions. See 37 CFR 1.142(b) and MPEP § 821.03.

***Priority***

7. The present application claims status as a CON of 09/606,369 filed June 28, 2000 which is a CIP of 09/473,904 filed December 28, 1999 (issued as U.S. Patent 6,858,394 on February 22, 2005) which is a CIP of 09/256,943 filed February 24, 1999 (issued as U.S. Patent 6,429,027 on August 6, 2002) which claims benefit of 60/113,968 filed December 28, 1998.

***Information Disclosure Statement***

8. The information disclosure statements (IDS) submitted on October 29, 2007 and December 17, 2007 are being considered by the examiner.

***Invention as Claimed***

9. An array of arrays comprising (a) a first substrate with a surface comprising a plurality of assay wells comprising samples and (b) a second substrate comprising a plurality of array

locations, each array location comprising a plurality of discrete sites on a single projection, wherein said sites comprise different bioactive agents, and wherein said plurality of array locations is configured as a plurality of projections to be dipped from above into said plurality of assay wells comprising samples and variations thereof.

10. “Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim.” *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969). Furthermore, “[i]nclusion of material or article worked upon by a structure being claimed does not impart patentability to the claims.” *In re Young*, 75 F.2d 996, 25 USPQ 69 (CCPA 1935) (as restated in *In re Otto*, 312 F.2d 937, 136 USPQ 458, 459 (CCPA 1963)). An apparatus must be distinguished from the prior art in terms of structure rather than function. See *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997); *In re Swinehart*, 439 F.2d 210, 212-13, 169 USPQ 226, 228-29 (CCPA 1971); *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959); and *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). See also MPEP § 2114 and § 2115. Thus, the samples are not provided patentable weight. In addition, the functional language “dipped from above” is not provided patentable weight. However, the structural information gleaned from the reagents and the functional limitations are provided patentable weight (i.e. first substrate must have the ability to hold samples; second substrate must be able to fit within the first substrate, etc.).

**Withdrawn Rejections**

11. The rejection of claims 29-32, 35-39, 41-42, 45-49, 51-52, 54-56, and 58-59 under 35 U.S.C. 102(b) as being anticipated by Rava et al. U.S. Patent 5,545,531 issued August 13, 1996 is withdrawn in view of the claim amendments received on October 29, 2007 (i.e. a second substrate comprising a plurality of projections wherein each projection comprises a plurality of different bioactive agents). Rava et al. teach individual arrays on the bottom of microtiter plates, thus the “projections” are not protruding from a single substrate. Rava et al. also teach bottomless microtiter plates (i.e. substrate is not able to hold samples).

12. The rejection of claims 29-32, 35-42, 45-52, and 55-56 under 35 U.S.C. 102(b) as being anticipated by Holmes U.S. Patent 5,549,974 issued August 27, 1996 is withdrawn in view of the claim amendments received on October 29, 2007 (i.e. a second substrate comprising a plurality of projections wherein each projection comprises a plurality of different bioactive agents). Holmes et al. either teaches multiple separate projections (i.e. multiple substrates) or a single bioactive agent on a single projection (i.e. pin) utilized to make bioactive agents.

13. The rejection of claims 29-52, 54-56, and 58 under 35 U.S.C. 102(e) as being anticipated by Felder et al. U.S. Patent 6,458,533 filed December 22, 1998 (effective filing date of December 19, 1997) is withdrawn in view of the claim amendments received on October 29, 2007 (i.e. a second substrate comprising a plurality of projections wherein each projection comprises a plurality of different bioactive agents).

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14. The rejection of claims 29-32, 35-42, 45-52, 54-56, and 58 under 35 U.S.C. 102(e) as being anticipated by Wang et al. U.S. Patent 5,922,617 filed November 12, 1997 is withdrawn in view of the claim amendments received on October 29, 2007 (i.e. a second substrate comprising a plurality of projections wherein each projection comprises a plurality of different bioactive agents).

15. The rejection of claims 29-58 under 35 U.S.C. 103(a) as being unpatentable over Felder et al. U.S. Patent 6,458,533 filed December 22, 1998 (effective filing date of December 19, 1997) and Walt et al. U.S. Patent 6,327,410 effective filing date March 14, 1997 is withdrawn upon further consideration.

16. The rejection of claims 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 40, 41, 42, 43, 44, 45, 46, 47, 48, and 50 on the provisional ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 37, 38, 39, 40, 42, 43, 44, 45, 49, 50, 51, 52, and 55 of copending Application No. 09/606,369 is withdrawn due to the abandonment of the application on October 17, 2007.

### New Rejections

#### *Claim Rejections - 35 USC § 102*

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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18. Claims 29-30, 35, 37-39, 41, 45, 47-49, and 51-59 are rejected under 35 U.S.C. 102(b) as being anticipated by Pinkel et al. WO 97/27326 published July 31, 1997 (provided by applicants in the IDS submitted October 29, 2007).

For present claims 29-30, 41, 53, 57, and 59, Pinkel et al. teach a first substrate comprising a plurality of assay wells comprising targets (i.e. molecules to be attached to the fiber optic strands) or probes (i.e. samples; hybridization chamber) and a second substrate comprising a plurality of array locations comprising a plurality of projections (i.e. fiber optic bundles and/or individual fiber optic strands) comprising different biological binding partners (i.e. bioactive agents) which can be “dipped” into the wells (i.e. room for three dimensional movement by hand; please refer to the entire specification particularly the abstract; Figures 1-5 and 6A-6B; pages 4-7 and 10-20). Please refer to MPEP § 2114 which states that the manner of operating a device does not differentiate an apparatus from the prior art (i.e. moved in three dimensions).

For present claims 35 and 45, Pinkel et al. teach biological binding partners including nucleic acids, nucleic acid analogs, antigens, antibodies, etc. (please refer to the entire specification particularly the abstract; pages 1, 4, 6, and 9).

For present claims 37-38 and 47-48, Pinkel et al. teach fiber optic sensors comprising 30,000 nucleic acids, fiber optic sensors with diameters of 5-500 micrometers, 1000-3000 fiber optic strands in a fiber optic sensor 0.5 mm in diameter, 1 million strands per square millimeter, and approximately 30,000 different biological binding partners per square millimeter (i.e.  $1 \text{ cm}^2 = 300,000$  different bioactive agents; please refer to the entire specification particularly pages 8 and 11).

For present claims 39, 49, 54, and 58, Pinkel et al. teach various methods of coupling the bioactive agents with the fiber optic strands including photolithography (i.e. direct coupling; please refer to the entire specification particularly pages 3 and 15-18).

For present claims 51 and 55, Pinkel et al. teach fiber optic bundles (i.e. "sticks"; please refer to the entire specification particularly Figures 2, 4, 5). Please note: the functional limitation (i.e. intended use) of stirring the sample is not provided patentable weight. Please refer to MPEP § 2106 section II. Language that suggests or makes optional but does not limit a claim to a particular structure does not limit the scope of a claim or claim limitation (i.e. intended use). Also refer to MPEP § 2114 which states that the manner of operating a device does not differentiate an apparatus from the prior art.

For present claims 52 and 56, Pinkel et al. teach the transmission faces of the optical fibers attached to a detector and cladding of the optical fibers (i.e. molded; please refer to the entire specification particularly Figure 4; pages 11 and 13-14).

Therefore, the presently claimed invention is anticipated by the teachings of Pinkel et al.

***Claim Rejections - 35 USC § 103***

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

20. Claims 29-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walt et al. U.S. Patent 6,406,845 filed May 5, 1997; Kercso et al. U.S. Patent 6,132,685 filed August 10,

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1998; and Walt et al. U.S. Patent 6,327,410 filed September 11, 1998 (effective filing date of March 14, 1997).

For present claims 29-30, 35, 41, 45, 53, and 57, Walt et al. teach a first substrate (i.e. eppendorf tube) comprising oligonucleotides or sample and a second substrate comprising a plurality of array locations (i.e. multiple optic fibers; projections) comprising different oligonucleotide probes (i.e. DNA, RNA, PNA; bioactive agent) which are dipped, submerged, or placed in an eppendorf tube (please refer to the entire specification particularly Figures 4, 5A-5B, 6-15, 17, 17A-17B, 18A-18B, 22A-22F; columns 4-5, 7-17; Experiments 1-9). Walt et al. teach a photopolymerization tube and a hybridization tube (i.e. first substrate and a hybridization chamber, respectively; please refer to the entire specification particularly column 10, Photopolymerization section and Experiment 1).

For present claim 39, 49, 54, and 58, Walt et al. teach photopolymerization of the DNA, RNA, or PNA probes directly to the fiber optic strands (please refer to the entire specification particularly columns 20-22, Photopolymerization section).

For present claims 51 and 55, Walt et al. teach fiber optic bundles dipped, submerged, or placed in eppendorf tubes (i.e. "sticks"; please refer to the entire specification particularly Figures 1, 4, 6, 10-15; Experiments 1-9). Please note: the functional limitation (i.e. intended use) of stirring the sample is not provided patentable weight. Please refer to MPEP § 2106 section II. Language that suggests or makes optional but does not limit a claim to a particular structure does not limit the scope of a claim or claim limitation (i.e. intended use). Also refer to MPEP § 2114 which states that the manner of operating a device does not differentiate an apparatus from the prior art.

For present claims 52 and 56, Walt et al. teach joining the fiber optic strands into a bundle (i.e. projections) via epoxy adhesives and cladding material and coupling the fiber optic strands to stainless steel tube and placed into a fiber chuck (i.e. molded substrate; please refer to the entire specification particularly columns 10-16, section I A; columns 27-28, section VI, Experimental Series A; and Experiment 1).

For present claim 59, Walt et al. teach x-y-z positioners (i.e. three dimensional movement; please refer to the entire specification particularly Figure 16; column 22, section III).

However, Walt et al. does not teach utilizing a microtiter plate (i.e. to hold the samples; multiple wells).

For present claims 31-34 and 42-44, Kercso et al. teach 96, 384, and 1536 well microtiter plates which hold reagents including samples (please refer to the entire specification particularly the abstract; Figures 7-8; columns 3, 7, and 11-12). In addition, Kercso et al. teach utilizing an x-y-z robotic arm to manipulate the microtiter plate and microfluidic device (please refer to the abstract; Figures 4 and 10; column 3, lines 13-25 and 51-67; column 9, lines 33-67; column 13, lines 25-67). Furthermore, Kercso et al. teach utilizing multiple fiber optics in multiple wells (i.e. at least 12 wells of a 96 well plate; please refer to the entire specification particularly Figures 9-10; columns 3, 5, and 13-14).

The claim would have been obvious because the substitution of one known element (i.e. eppendorf tube taught by Walt et al.) for another (i.e. multiwell plate taught by Kercso et al.) would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Please refer to *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007).

However, neither Walt et al. (U.S. Patent 6,406,845) nor Kercso et al. teach microspheres or the density of the bioactive agents.

For present claims 36-38 and 46-48, Walt et al. teach 10,000,000 to 2,000,000,000; 100,000 to 10,000,000; and 10,000 to 100,000 bioactive agents per square centimeter (please refer to the entire specification particularly column 5, lines 4-31).

For present claims 40 and 50, Walt et al. teach microspheres associated with each fiber optic strand (please refer to the entire specification particularly the abstract; Figures 5B, 7A-7B, 8A-8C, 9A-9B, and 10A-10B; columns 3, 5-7).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to alter the fiber optic bundles taught by Walt et al. (U.S. Patent 6,406,845) with the fiber optic bundles holding microspheres taught by Walt et al. (U.S. Patent 6,327,410).

One having ordinary skill in the art would have been motivated to do this because Walt et al. (U.S. Patent 6,327, 410) teach that utilizing microspheres with fiber optic arrays allows for more rapid deposition of probes onto microspheres instead of directly on fiber optic bundles and allows for higher density of probes on the microsphere instead of directly on the fiber optic bundle (please refer to column 3, lines 13-26; paragraph spanning columns 4-5; and column 5, lines 24-31).

One of ordinary skill in the art would have had a reasonable expectation of success in the modification of the fiber optic bundles taught by Walt et al. (U.S. Patent 6,406,845) with the fiber optic bundles holding microspheres taught by Walt et al. (U.S. Patent 6,327,410) because of the working example provided by Walt et al. (U.S. Patent 6,327,410) utilizing microspheres on the ends of fiber optic bundles (please refer to Example I).

the working example provided by Walt et al. (U.S. Patent 6,327,410) utilizing microspheres on the ends of fiber optic bundles (please refer to Example I).

Therefore, the presently claimed array of arrays is rendered *prima facie* obvious by the teachings of Walt et al. (U.S. Patent 6,406,845), Kercso et al., and Walt et al. (U.S. Patent 6,327,410).

#### **Maintained Rejections**

21. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Please note: the rejections may have been altered to reflect the claim amendments received on October 29, 2007.

#### ***Double Patenting***

22. Claims 29-59 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 7-9, 12-18, 24, 25, 26, 27, 28, 29, and 30 of U.S. Patent No. 6,429,027. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the presently claimed invention and the claims of U.S. Patent 6,429,027 are drawn to an array comprising a microtiter plate with wells (e.g. first substrate) and microbeads (e.g. second substrate) with bioactives wherein the microbeads may be suspended from fiber optic bundles (i.e. projections).

For present claims 29-30, 39, 41, and 49, U.S. Patent 6,429,027 claims a composite array (e.g. array of arrays) comprising a substrate with a plurality of assay locations with discrete sites which can be wells of a microtiter plate (e.g. first substrate which also may act as a hybridization chamber) and a population of microspheres (e.g. a second substrate) with bioactive agents wherein each microsphere is suspended from an individual fiber of a fiber optic bundle (i.e.

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bundles may be dipped (please refer to claim 9; column 4, lines 53-62). An apparatus must be distinguished from the prior art in terms of structure rather than function (i.e. dipping from above). See *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997); *In re Swinehart*, 439 F.2d 210, 212-13, 169 USPQ 226, 228-29 (CCPA 1971); *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959); and *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990).

For present claim 31-34 and 42-44, U.S. Patent 6,429,027 claims wells of a microtiter plate wherein the microtiter plates or composite array of the claims are defined in the specification as having 96, 384, or 1536 wells (please refer to claims 3 and 8; column 4, lines 17-32; column 6, lines 44-64).

For present claims 35 and 45, U.S. Patent 6,429,027 claims the bioactive agents are nucleic acid, nucleic acid analogs, or protein (please refer to claims 12, 13, 25, 26, 27, 28, 29, 30).

For present claims 36-38 and 46-48, U.S. Patent 6,429,027 claims 1000 discrete sites per  $\text{cm}^2$ , 1,000,000 sites/ $\text{cm}^2$ , and 10,000 discrete sites and the specification further states that the array can have higher densities including from about 10,000,000 to about 2,000,000,000 candidate agents (i.e. bioactive agents) per square centimeter (please refer to claims 15-24; column 6, lines 1-33).

For present claims 40 and 50, U.S. Patent 6,429,027 claims microspheres with bioactive agents coupled to fiber optic fibers in a bundle (please refer to claims 1, 7, and 9).

For present claims 51 and 55, U.S. Patent 6,429,027 claim fiber optic bundles comprising microspheres and microtiter plates (i.e. sticks that stir the sample in the assay wells; please refer

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to claims 1, 3, 7, 8, and 9). “Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim.” *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969). Furthermore, “[i]nclusion of material or article worked upon by a structure being claimed does not impart patentability to the claims.” *In re Young*, 75 F.2d 996, 25 USPQ 69 (CCPA 1935) (as restated in *In re Otto*, 312 F.2d 937, 136 USPQ 458, 459 (CCPA 1963)). An apparatus must be distinguished from the prior art in terms of structure rather than function. See *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997); *In re Swinehart*, 439 F.2d 210, 212-13, 169 USPQ 226, 228-29 (CCPA 1971); *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959); and *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). See also MPEP § 2114 and § 2115. Thus, the samples are not provided patentable weight. In addition, the functional language “used as sticks that stir the sample” is not provided patentable weight (i.e. structure of “sticks” is claimed via the fiber optic bundles; please refer to claim 9).

For present claims 52-53 and 56-57, U.S. Patent 6,429,027 claims fiber optic bundles (i.e. molded substrate comprising projections; please refer to claim 9).

For present claims 54 and 58, U.S. Patent 6,429,027 claims arrays wherein the specification teaches that the arrays may be made by photolithography (please refer to claims 1 and 7; column 8, lines 16-28). This limitation is considered a product-by-process limitation (i.e. method of making the array apparatus; please refer to MPEP § 2113).

For present claim 59, U.S. Patent 6,429,027 claim fiber optic bundles wherein the specification teaches that the fiber optic bundles may be dipped (i.e. three dimensional

For present claim 59, U.S. Patent 6,429,027 claim fiber optic bundles wherein the specification teaches that the fiber optic bundles may be dipped (i.e. three dimensional movement by hand; please refer to claim 9; column 4, lines 53-62; column 7, lines 14-25; column 8, lines 1-15). An apparatus must be distinguished from the prior art in terms of structure rather than function (i.e. three dimensional movement). See *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997); *In re Swinehart*, 439 F.2d 210, 212-13, 169 USPQ 226, 228-29 (CCPA 1971); *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959); and *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990).

Therefore, the presently claimed invention is obvious over the claims of U.S. Patent 6,429,027.

*Arguments and Response*

23. Applicants' arguments directed to the rejection on the ground of nonstatutory obviousness-type double patenting over claims 1-4, 7-9, 12-18, 24, 25, 26, 27, 28, 29, and 30 of U.S. Patent No. 6,429,027 for present claims 29-59 were considered but are not persuasive for the following reasons.

Applicants contend that U.S. Patent No. 6,429,027 does not claim a plurality of projections to be dipped from above into said plurality of assay wells comprising samples.

Applicants' arguments are not convincing since the claimed invention of U.S. Patent No. 6,429,027 render the instant claims *prima facie* obvious. U.S. Patent No. 6,429,027 claims a composite array composition comprising a first substrate which may be wells comprising a plurality of assay locations, a second substrate comprising a plurality of array locations which

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may be fiber optic bundles (i.e. projections) wherein each fiber of the fiber optic bundle comprises a microsphere (please refer to claims 7-9). In addition, U.S. Patent 6,429,027 claims fiber optic bundles wherein the specification teaches that the fiber optic bundles may be dipped (please refer to claim 9; column 4, lines 53-62). An apparatus must be distinguished from the prior art in terms of structure rather than function (i.e. dipping from above). See *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997); *In re Swinehart*, 439 F.2d 210, 212-13, 169 USPQ 226, 228-29 (CCPA 1971); *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959); and *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). Furthermore, “[e]xpressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim.” *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969). Furthermore, “[i]nclusion of material or article worked upon by a structure being claimed does not impart patentability to the claims.” *In re Young*, 75 F.2d 996, 25 USPQ 69 (CCPA 1935) (as restated in *In re Otto*, 312 F.2d 937, 136 USPQ 458, 459 (CCPA 1963)). See also MPEP § 2114 and § 2115. Thus, the samples are not provided patentable weight.

24. Claims 29, 35, 39-41, 45, and 49-58 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 and 16-23 of copending Application No. 10/363,240. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the presently claimed invention and the claims of Application 10/363,240 are drawn to arrays comprising a (first) substrate with wells and a second substrate or cells with bioactives on the surface.

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For present claims 29, 39-41, 49-51, 55, Application 10/363,240 claims a substrate with fiber optic bundles comprising microspheres and cells (i.e. second substrate with projections) and a substrate (please refer to claims 1-3 and 16-18).

For present claims 35 and 45, Application 10/363,240 claims that the cells can bind an antibody ligand or the cells comprise a binding partner, peptide, or candidate agents (please refer to claims 4-7).

For present claims 52-53 and 56-57, Application 10/363,240 claims fiber optic bundles (please refer to claim 2).

For present claims 54 and 58, Application 10/363,240 claims photolabile linkage (e.g. photolithographic; please refer to claims 20 and 23).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

*Arguments and Response*

25. Applicants' arguments directed to the rejection on the ground of provisional nonstatutory obviousness-type double patenting over claims 1-7 and 16-23 of U.S. Application No. 10/363,240 for present claims 29, 35, 39-41, 45, and 49-58 were considered but are not persuasive for the following reasons.

Applicants contend that they will consider amending and/or canceling claims in one or both applications or filing a terminal disclaimer. However, the claim amendments have not overcome the provisional nonstatutory obviousness-type double patenting. Therefore the rejection is maintained.

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***Future Communications***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amber D. Steele whose telephone number is 571-272-5538. The examiner can normally be reached on Monday through Friday 9:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Doug Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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AU1639

January 7, 2008

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